UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *et al.*, *ex rel.* ZACHARY SILBERSHER, **Plaintiffs,** **v.** **JANSSEN BIOTECH, INC., *et al.*,** **Defendants.**	**Civil Action No. 19-cv-12107-MEF-SDA** **SPECIAL MASTER ORDER**

THIS MATTER having come before the undersigned Special Master appointed by Order entered on March 18, 2024 (ECF No. 331); and the Order providing that the Special Master "shall oversee the schedule for completion of discovery, and all discovery disputes and motions related thereto, pursuant to procedures for practice that the Special Master may establish and modify as necessary", *id.* at 2, ¶ 2; and the Special Master, in an effort to address and resolve the parties' respective discovery disputes, having entered an Order on April 12, 2024 (ECF No. 337) setting deadlines for submissions relating to "[e]ach party's first set of unresolved discovery issues" along with "[e]ach party's second set of unresolved discovery issues", *id.* at 1, ¶¶ 2-3; and the Special Master having considered the issues, arguments, and positions submitted as to Relator's request "to order Defendants to provide Rule 30(b)(6) corporate representatives" as set forth in: (1) Relator's submission of April 26, 2024 ("Application to Compel") (ECF No. 340) and (2) Defendants' response of May 3, 2024 (ECF No. 349); and good cause appearing for the entry of this order

IT IS on this **10th** day of **July 2024 ORDERED** as follows:

1. Relator's Application to Compel is **GRANTED IN PART AND DENIED IN PART**.

2. Certain depositions of Defendants' 30(b)(6) designees – consistent with the Special Master's determinations as set forth in this Order – are **ORDERED** to proceed. Within ten (10) days of the entry of this Order, the parties are directed to meet, confer, and schedule these depositions.

SPECIAL MASTER DECISION

The Special Master presumes the parties are well acquainted with the pertinent facts and procedural history of this matter. Before the Special Master is Relator's Application to Compel, which specifically requests an Order compelling Defendants to designate and produce Rule 30(b)(6) corporate representatives on disputed topics. (ECF No. 340.) Defendants submitted a response to Relator's letter on May 3, 2024 arguing, on various grounds, that having to prepare and produce 30(b)(6) designees as to the disputed topics would be improper and should not be ordered. (ECF No. 349.)

I. Relator's Submission of April 26, 2024 (ECF No. 340)

Relator requests that the Special Master order Defendants to produce Rule 30(b)(6) corporate representatives to testify with respect to certain topics, (ECF No. 340, p. 9), which specifically consist of the following:

- Topic 12 covers "[t]he roles, rights, and responsibilities of each corporate entity that is a direct or indirect subsidiary of Johnson & Johnson, including [the three Defendant Janssen subsidiaries], that participated in the research, development, manufacture, marketing, or sale of Zytiga." *Id.* at 10.

- Topic 13 covers the "role, rights, and responsibilities of each Defendant relating to the '340 Application (for the allegedly fraudulent '438 Patent), the '440 Application (which was a discontinued application claiming the same inventions as the '340 Application), the '213 Patent (the original chemical compound patent), and the '438 Patent." *Id.*

- Topics 15, 16, 19 and 20 cover: the "acquisition, license, or transfer of any Right related to the '438 Patent" (Topic 15); any "actions taken by Johnson & Johnson to enforce the '438 Patent, and any benefits derived by Johnson & Johnson" from such enforcement (Topic 16); each Defendant's "expectations, goals, and strategy with respect to launching a coated version of Zytiga (Topic 19); each Defendant's "expectations, goals, and strategy with respect to launching a 500 mg version of Zytiga" (Topic 20). *Id.* at 11-12.

- Topic 18 covers the sale of the authorized generic of Zytiga, including contracts, licenses, and control of the right to sell the authorized generic, and Defendants' goals and expectations as to the sale of an authorized generic. *Id.* at 13.

- Topics 25 and 26 cover "negotiation and terms of any settlement with generic competitors sued for patent infringement relating to Zytiga" (Topic 25) and the "negotiation and terms of any exclusive pharmacy agreements that was intended to, or had the effect of, maintaining or protecting Zytiga's market share against generic competition". *Id.*

Relator claims Defendants have refused to provide designees with respect to these topics and challenges Defendants' objections as improper. *Id.* at 9-10.

As to Topic 12, Relator argues that the information related to Johnson & Johnson's subsidiaries is "undoubtedly know[n]" to Defendants and that they "should not be allowed to hide that information behind feigned ignorance regarding what this topic is intended to cover." *Id.* at 10.

As to Topic 13, Relator states that the information sought with respect to the "specific role(s) that each defendant played relating to the referenced applications and patents" is, contrary to Defendants' assertion, not duplicative of Topics 1, 2, and 3. *Id.* at 10-11. Relator classifies Topics 15, 16, 19 and 20 as "highly relevant and straightforward" and notes that testimony on these issues "may help establish liability by one or more Defendants for the claims in this action, as well as the amount of damages." *Id.* at 11-12.

As to Topic 18, relating to the sale of the authorized generic of Zytiga, Relator notes that Defendants "have offered to provide a designee to testify only as to the actual sales of Authorized Generics," yet further information regarding "control over the timing and amount of authorized

generic sales, and the independence of the authorized generic manufacturer" are "relevant to the potential variability" of generic sales in different scenarios. Relator claims he is thus entitled to examine Defendants' designees on this topic. *Id.* at 13.

Topics 25 and 26 relate to negotiations surrounding any settlement with generic competitors sued by Defendants for patent infringement relating to Zytiga (Topic 25), and Defendants' exclusive pharmacy agreements protecting Zytiga's market share against generic competitors (Topic 26). Relator highlights his entitlement to the above information noting that each "implicate[s] issues at the heart of this action" and relates to information including "whether and how Defendants' used the '438 Patent to forestall generic competition," and "restrict access of generic competitors to distribution channels, suppressing generic entry." *Id.*

II. Defendants' Response of May 3, 2024 (ECF No. 349)

In response, Defendants claim that Relator's discovery requests and the Rule 30(b)(6) topics at issue contain "multiple overbroad, overlapping, and unnecessarily burdensome requests for information" regarding Defendants' corporate structure and their "roles, rights, and responsibilities." (ECF No. 349, p. 3.) Defendants note they have already provided designees with respect to seventeen (17) of twenty-six (26) of Relator's Rule 30(b)(6) topics[1], and Defendants' Rule 30(b)(6) depositions proceeded on April 11, 2024. *Id.* at. 4-5. Defendants note that Relator served a subsequent Rule 30(b)(6) notice with the additional topics at issue in the "waning weeks of discovery" and that Relator has "refused to modify" any of the nine disputed topics despite the parties meeting and conferring. *Id.* at 16. Defendants ask the Special Master to deny Relator's "exceedingly broad" discovery requests at this "late stage" in discovery. *Id.*

[1] Topics 1-11, 14, 17, and 21-24 are not in dispute. (*See* ECF No. 340, pp. 9-14.)

Specifically, Defendants contend Topic 12 is "cumulative of written requests to which Defendants have responded," is "undefined, vague, and ambiguous," and is "excessive, unduly burdensome, and disproportionate to the needs of the case." *Id.* at 4-5. Topic 13 "suffers from all the same defects" as Topic 12, is duplicative of Topics 1 to 3, and is irrelevant as it seeks testimony relating the post-prosecution roles of Defendants despite Relator's Complaint alleging that the fraud occurred "during the patent prosecution, not afterwards." *Id.* at 5-6.

As to Topic 15, Defendants claim this topic is cumulative of written discovery requests to which Defendants have already responded, and specifically direct the Special Master to Relator's Request for Admission No. 6, and Relator's Request for Production No. 53. Defendants contend they have already provided the information Relator seeks as to Topic 15. *Id.* at 7. Additionally, Defendants represent they will not argue that Relator failed to name a necessary J&J party with "rights" to the '438 Patent. *Id.*

As to Topic 16, Defendants contend this topic suffers from "multiple deficiencies", as it is: (1) facially overbroad and unduly burdensome by failing to define "any actions," "enforce," "enforcement" or "benefits"; (2) wholly irrelevant to this case because it seeks information relating to Defendants' attempts to enforce the patent in subsequent litigation with the focus of the current litigation surrounding "whether Defendants procured the '438 Patent by fraud,"; and (3) despite Defendants' objection to this topic as raised in Relator's other discovery requests "more than two years ago," Relator has "made no subsequent attempt to resolve these objections" and now "attempt[s] to seek the same irrelevant information through Rule 30(b)(6) deposition testimony[.]" *Id.* at 17-18.

As to Topics 18, 19, 20, and 26, Defendants argue these topics "all suffer from the same crucial flaw" and are "untethered" to Relator's Complaint. *Id.* at 18. Defendants characterize these

topics as "just the latest of Relator's many attempts to fish for irrelevant information at the close of discovery," and not a proper use of Rule 30(b)(6). *Id.* Defendants highlight that a keyword search of the Complaint finds no mention of the above four topics and that they are "plainly irrelevant to this False Claims Act case[.]" *Id.* at 19.

As to Topic 25, Defendants highlight the irrelevance of the negotiation of any settlement agreements with generic competitors. Defendants also note that issues regarding this topic could have been resolved "far earlier" as Defendants raised objections on similar issues "more than a year ago" with Relator making no effort to resolve those objections, thus leading to an improper request in the form of a Rule 30(b)(6) topic. *Id.* at 19-20.

III. Legal Standard

Pursuant to Fed.R.Civ.P. 30(b)(6), "a party may take a deposition of an individual who is designated to testify on behalf of a company, corporation or government agency." *Harris v. New Jersey*, 259 F.R.D. 89, 92 (D.N.J. 2007). "A corporation has an affirmative duty to produce a representative who can answer questions that are within the scope of the matters described in the notice." *Id.* A Rule 30(b)(6) deponent "is required to know the answers, and the buck stops with him/her." *Bracco Diagnostics Inc. v. Amersham Health Inc.*, No. 03-cv-06025, 2005 WL 6714281, at *2 (D.N.J. Nov. 7, 2005). The representative's testimony "is binding on the entity and goes beyond the scope of the individual's personal knowledge." *Harris*, 258 F.R.D at 92.

A party seeking discovery by way of Rule 30(b)(6) has a duty to "inform the organization to be deposed about the subject matter of the deposition testimony," and "must describe with reasonable particularity the matters for examination." *Fed. Trade Comm'n v. Am. Future Sys.*, No. 20-cv-02266, 2022 WL 1437562, at *2 (E.D. Pa. Apr. 8, 2022). Although "[n]o judicial consensus exists concerning what 'reasonable particularity' means," topics that seek to "lump together

unrelated or marginally related subject matter," and those that "leave a witness in doubt about the metes and bounds of the subject matter concerning which he or she must testify" are frequently stricken for lacking reasonable particularity. *Id.*

Additionally, courts have denied requests for Rule 30(b)(6) topics when the information sought is duplicative, cumulative of prior discovery, or more appropriately discoverable through other means. *See*, *e.g.*, *State Farm Mut. Auto. Ins. Co. v. New Horizont, Inc.*, 250 F.R.D. 203, 208 (E.D. Pa. 2008); *Johnson v. Geico Cas. Co.*, 269 F.R.D. 406, 415-16 (D. Del. 2010); *Tr. of Boston Univ. v. Everlight Elec. Co., Ltd.*, No. 12-cv-11935, 2014 WL 5786492, at *4 (D. Mass. Sept. 24, 2014) ("A party may properly resist a Rule 30(b)(6) deposition on the grounds that the information sought is more appropriately discoverable through contention interrogatories and/or expert discovery.").

Rule 26(b)(1) defines the scope of topics a 30(b)(6) witness can be expected to testify to and "allows a party to obtain information concerning any matter, not privileged, which is relevant to the subject matter involved in the pending action." *New Jersey Dep't of Env't Prot. v. Am. Thermoplastics Corp.*, No. 98-cv-04781, 2017 WL 498710, at *2 (D.N.J. Feb. 7, 2017). Rule 30(b)(6) does not carve an exception into Rule 26, and thus, a "deponent must answer discovery requests coextensive with the requirements of Fed.R.Civ.P. 26 discovery." *Bracco*, 2005 WL 6714281, at *2.

IV. Special Master's Decision

The Special Master finds that Relator's Application to Compel should be granted in part and denied in part, consistent with the determinations set forth below. Defendants are directed to prepare and produce designees as to certain of the topics set forth in Relator's latest Rule 30(b)(6) Notice, subject to the parameters of the Special Master's rulings herein.

At the outset, the Special Master notes that Defendants have provided, or will provide, designees to testify as to seventeen (17) of twenty-six (26) of Relator's 30(b)(6) topics. (ECF No. 349, p. 4.) Defendants state that Relator already deposed Defendants' Rule 30(b)(6) designees on certain topics on April 11, 2024.

a. Topic 12.

Topic 12 seeks 30(b)(6) testimony on the "roles, rights, and responsibilities of each corporate entity that is a direct or indirect subsidiary of Johnson & Johnson, including [the Defendant Janssen subsidiaries], that participated in the research, development, manufacture, marketing, or sale of Zytiga." (ECF No. 340, p. 10; ECF No. 349, p. 4.) Defendants have represented that they have already responded to written discovery requests that are "cumulative" and thus overlap with the subject matter of Topic 12. Also, Relator deposed Defendants' Rule 30(b)(6) designees on certain topics on April 11, 2024 and Defendants have represented that this included "other corporate structure topics" which, as argued, overlap at least to some degree with Topic 12. (ECF No. 349, p. 5.)

The Special Master finds that Topic 12 is cumulative of other written discovery exchanged between the parties. Relator's request as to Topic 12 is denied.[2]

b. Topic 13.

Topic 13 seeks testimony on the "role, rights, and responsibilities" of each Defendant "relating to the '340 Application, the '440 Application, the '213 Patent, and the '438 Patent". *Id.* at 4-5. While disputing the relevance of Topic 13, Defendants also submit that Topic 13 is duplicative of Topics 1, 2, and 3, for which Defendants already provided Rule 30(b)(6) testimony.

[2] As to the "written discovery" referenced by Defendants in their response, (ECF No. 349, p. 4), Relator may raise any unresolved issues as to same with the Special Master after meeting and conferring with Defendants.

Id. at 6. Relator counters that Topic 13 is not duplicative of Topics 1, 2, and 3. Topic 1 relates to "Defendants' prosecution of all applications leading to the '438 Patent, including the '340 and '440 Applications"; Topic 2 relates to "Defendants' due diligence relating to the Commercial Success Argument prior to submitting that argument to the Patent Office"; and Topic 3 relates to "[a]ll facts, issues, and materials that Defendants relied upon or considered in making the Commercial Success Argument". (ECF No. 340, pp. 10-11.)

Insofar as Defendants argue that Topic 13 has "all the same defects" as Topic 12, which included Defendants' contention that "roles, rights, and responsibilities" is undefined, vague, and ambiguous, the Special Master agrees. The Special Master has not been presented with full copies of Relator's 30(b)(6) Notice (or Notices), Defendants' responses or objections, or other related items including instructions and definitions. Still, based on the present record on this dispute, the Special Master takes the view that Topic 13 is expansive, and thus, excessive and unduly burdensome.

However, the Special Master directs the parties to meet and confer on appropriate limitations to Topic 13 such that: (1) the "reasonable particularity" requirement as to Topic 13 is satisfied; and (2) Topic 13 is narrowed so as not to overlap with Topics 1, 2, and 3. If the parties are unable to stipulate to the foregoing parameters and complete a limited examination of Defendants' designee as to this topic, the parties shall promptly inform the Special Master.

c. Topic 14.

Defendants do not object or oppose Topic 14, and do not address Topic 14 in their response to Relator's Application to Compel. Accordingly, Relator's request as to Topic 14 is granted. Defendants are directed to prepare and produce a Rule 30(b)(6) designee for examination as to Topic 14.

d. Topic 15.

Topic 15 relates to the "acquisition, license, or transfer of any Rights related to the '438 Patent." (ECF No. 349, pp. 6-7.) Defendants contend this topic is cumulative of Relator's prior written discovery requests for which Defendants provided responses. Defendants refer to Relator's Request for Admission No. 6 and Relator's Request for Production No. 53 as examples. *Id.* at 7. Relator argues that Topic 15 is "important" because it will "reveal how rights related to the '438 Patent were held or transferred between and among Johnson & Johnson and its subsidiary corporate entities that were involved with Zytiga." (ECF No. 340, p. 12.) Relator adds that testimony on Topic 15 "may help establish" liability. *Id.* Relator has not addressed, through a supplemental submission or other reply, Defendants' contention that Topic 15 is cumulative of other discovery.

The Special Master finds that Topic 15 is cumulative of other written discovery exchanged between the parties. Thus, Relator's request as to Topic 15 is denied.

e. Topic 16.

Topic 16 relates to "[a]ny actions taken by Johnson & Johnson to enforce the '438 Patent, and any benefits derived by Johnson & Johnson from enforcement of the '438 Patent." (ECF No. 349, p. 17.) In addition to arguing that this topic is overbroad and burdensome, Defendants also question the relevance of this topic. They add that Defendants' subsequent enforcement litigation as to the patent was appropriate, as this has already been answered in prior antitrust litigation involving the parties. Defendants add that Relator served prior discovery requests on this topic, Defendants raised objections, and Relator made no other effort to timely address or resolve those objections. Relator argues that Topic 15 is "important" because it will "show what Johnson & Johnson … did to enforce the '438 Patent and what benefits it obtained from the enforcement."

(ECF No. 340, p. 12.) Relator adds that testimony on Topic 16 "may help establish" liability. *Id.* As with Topic 15, Relator has not addressed, through a supplemental submission or other reply, Defendants' contention that Topic 16 is cumulative of other discovery.

The Special Master finds that Topic 16 is cumulative of other written discovery exchanged between the parties. Thus, Relator's request as to Topic 16 is denied.

f. Topic 18.

Topic 18 relates to the sale of authorized generics of Zytiga, and Johnson & Johnson's "goals[,] expectations, and strategy with respect to the sale of Authorized Generics." (ECF No. 349, p. 18.) Defendants dispute the propriety of this topic for the same reasons argued as to Topics 19 and 20. Relator contends that the sale of the authorized generic of Zytiga, including contracts, licenses, and control of the right to sell generics, and Defendants' goals and expectations as to same, are proper topics for examinations under Rule 30(b)(6). Relator adds that Defendants' control over the timing and amount of such sales and independence of authorized generic manufacturers is "relevant to the potential variability of authorized generic sales given different but-for scenarios." (ECF No. 340, p. 13.)

The Special Master finds that Relator should be permitted to explore these issues through 30(b)(6) depositions. Thus, Relator's request as to Topics 18 is granted. Defendants are directed to prepare a Rule 30(b)(6) designee, or designees, for examination as to Topic 18.

g. Topics 19 and 20.

Topic 19 relates to Johnson & Johnson's expectations, goals, and strategy with respect to launching a coated version of Zytiga. (ECF No. 349, p. 18.) Topic 20 relates to Johnson & Johnson's expectations, goals, and strategy with respect to launching a 500 mg version of Zytiga. *Id.* at 18-19. Defendants argue these topics are "untethered" to Relator's Complaint and relate to

"new theories" of liability. Defendants argue that Topics 19 and 20 are irrelevant to Relator's False Claims Act allegations and instead pertain to a distinct antitrust theory which Defendants describe as "product hopping" to maintain patent exclusivity through successive periods. *Id.* at 19. Relator argues that Topics 19 and 20 are "important" because Defendants' launch of coated Zytiga (and, presumably, the 500 mg version of Zytiga that for Topic 20) was intended to suppress generic entry in anticipation of losing the patent infringement litigation and thus is "highly" relevant to Defendants' belief in the validity of the patent asserted against generic competitors.

The Special Master finds that Relator should be permitted to explore these issues through Rule 30(b)(6) depositions. Thus, Relator's request as to Topics 19 and 20 is granted. Defendants are directed to prepare a Rule 30(b)(6) designee, or designees, for examination as to Topics 19 and 20.

h. Topic 25.

Topic 25 relates to the "negotiation of any settlement with generic competitors sued for patent infringement relating to Zytiga." (ECF No. 349, p. 19.) Defendants represent they have previously agreed to produce the actual settlement agreements but otherwise objected to Relator's Request for Production on this subject. Relator claims he is entitled to "inquire into any settlements Defendants reached with generic competitors because they would implicate issues at the heart of this action[[.]" (ECF No. 340, p. 13.)

The Special Master finds that Topic 25 is cumulative of other written discovery that may not have yet been exchanged between the parties. Thus, Relator's request as to Topic 25 is denied. However, Defendants are directed to produce the settlement agreements referenced in their response, (ECF No. 349, p. 20), within seven days of the entry of this Order.

i. Topic 26.

Topic 26 relates to the negotiation and terms of any exclusive pharmacy agreements intended to maintain or protect (or having the effect of maintaining or protecting) Zytiga's market share against generic competition. Defendants dispute the propriety of this topic for the same reasons argued as to Topics 19 and 20. (ECF No. 349, pp. 18-19.) Relator claims he is entitled to "inquire into any exclusive pharmacy agreements" covered within Topic 26 because such agreements are, according to Relator, "often used by brand companies to restrict access of generic competitors to distribution channels, suppressing generic entry." (ECF No. 340, p. 13.)

The Special Master finds that Relator should be permitted to explore these issues through 30(b)(6) depositions. Thus, Relator's request as to Topics 26 is granted. Defendants are directed to prepare a Rule 30(b)(6) designee, or designees, for examination as to Topic 26.

V. Conclusion

For the reasons set forth above, Relator's Application to Compel is **GRANTED IN PART AND DENIED IN PART**, consistent with the rulings set forth above.

IT IS SO ORDERED.

Dated: July 10, 2024

s/ Douglas E. Arpert
DOUGLAS E. ARPERT
SPECIAL MASTER